

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PFIZER INC.,)	
)	
Plaintiff,)	
)	
v.)	1:05CV39
)	
SYNTHON HOLDING, B.V.;)	
SYNTHON, B.V.;)	
SYNTHON PHARMACEUTICALS, LTD.;)	
and SYNTHON LABORATORIES, INC.,)	
)	
Defendants.)	

MEMORANDUM OPINION

BEATY, District Judge.

This case is a patent infringement action brought by Plaintiff Pfizer Inc. (“Plaintiff”) against Defendants Synthon Holding, B.V., Synthon, B.V., Synthon Pharmaceuticals, Ltd., and Synthon Laboratories, Inc. (“Defendants”). The matter is presently before the Court on two motions: (1) Defendant Synthon Laboratories’ (“Synthon Labs”) Motion to Transfer or Dismiss [Document #12] based on its contention that this Court does not have personal jurisdiction over it; and (2) Defendants’ Motion to Transfer [Document #21] pursuant to 28 U.S.C. § 1404(a) based on their contention that the Eastern District of Virginia is a more convenient forum.

As discussed below, the Court finds that Synthon Labs had significant contact with North Carolina and worked with affiliated entities in North Carolina to prepare and submit an Abbreviated New Drug Application (“ANDA”). This lawsuit arises directly out of that ANDA and those contacts. Therefore, this Court has specific personal jurisdiction over Synthon Labs with respect to this patent infringement claim. In addition, the Court finds that Synthon Labs was dominated and controlled by the other Synthon entities, and is the “alter ego” of the Synthon entities in North

Carolina. Therefore, this Court has personal jurisdiction over Synthon Labs as the alter ego of the North Carolina entities. For both of these reasons, Defendant Synthon Labs' Motion to Dismiss or Transfer will be denied. With respect to the Motion to Transfer made pursuant to 28 U.S.C. § 1404(a), the Court concludes that Defendants have failed to demonstrate that the Eastern District of Virginia would be a more appropriate or convenient forum, and the Court finds that the balancing of factors favors retaining venue in this Court. Therefore, Defendants' Motion to Transfer pursuant to 28 U.S.C. § 1404(a) will also be denied.

I. FACTUAL BACKGROUND

Plaintiff holds two patents related to its heart medication Norvasc: the '303 patent and the '909 patent. The '909 patent expires on January 31, 2007. The '303 patent expires on September 28, 2007. Synthon Labs filed an ANDA for a generic equivalent to Norvasc on March 5, 2004. The ANDA was accepted by FDA for substantive review on December 23, 2004. The ANDA included a "Paragraph IV certification" which alleged that the '909 patent is invalid and that the '303 patent is not infringed by Synthon's generic product.¹ With respect to the present Motions to Transfer, the Court makes the following factual findings.

The ANDA at issue in this case was prepared by Defendant Synthon Pharmaceuticals, Ltd. ("Synthon Pharma") in North Carolina. Synthon Pharma is a North Carolina corporation with its principal place of business in North Carolina. Synthon Pharma is a subsidiary of Defendant Synthon Holding, B.V. ("Synthon Holding"). Synthon Holding is a privately-held Dutch company

¹ These patents have also been challenged by unrelated parties in several ongoing lawsuits. The first generic ANDA filer was Mylan Laboratories, and Plaintiff filed an infringement suit against Mylan on September 20, 2002 in the Western District of Pennsylvania. The suit involving Mylan Laboratories is still ongoing at this time.

owned and controlled by Dr. Jacques Lemmens. Synthon Holding has over 20 wholly-owned direct or indirect subsidiaries. All of the Synthon defendants in this suit are wholly-owned direct or indirect subsidiaries of Synthon Holding. The Synthon organization in the United States is headquartered in North Carolina. Dr. Lemmens serves as President of Synthon Holding and CEO of Synthon Pharma, in addition to other positions with other of the Synthon entities.

Synthon Pharma began work on the ANDA at issue in 2002. From 2002 through 2004, Synthon Pharma did substantially all of the work in preparing and coordinating the ANDA. In a 2002 Agreement between Synthon Pharma and Synthon Research Ltd., Synthon Pharma was granted ownership of any ANDA resulting from any work under the agreement. During this time frame, Synthon Pharma contracted for, coordinated, and supervised the manufacture and testing of the ANDA product. Synthon Pharma also contracted for, supervised, and monitored the necessary bioequivalence studies. Synthon Pharma compiled, formatted and assembled this information into the ANDA. All of this work by Synthon Pharma was undertaken in North Carolina.

While this work was being done by Synthon Pharma, Mr. Joe Marchetti was a Vice President at Synthon Pharma in North Carolina. In late 2003, Dr. Lemmens decided to establish Synthon Labs as a new corporate entity in Virginia. According to Mr. Marchetti, Dr. Lemmens approached him and said “I’m thinking about setting up a new company [Synthon Labs] . . . are you interested in running that company?” (Dep. of J. Marchetti at 49.) Mr. Marchetti agreed, and beginning on January 1, 2004, Mr. Marchetti became the sole officer, director, and employee of Synthon Labs. Mr. Marchetti moved to Virginia and set up a small single-room office in Virginia for Synthon Labs. Synthon Labs was initially capitalized by a sale of 100 shares of common stock for \$150,000 to

another Synthon entity, Synthon Luxembourg Holding. Synthon Labs' 2004 financial statement was prepared by officers and attorneys of Synthon Holding. Mr. Marchetti testified that Synthon Research Ltd., another Synthon entity, agreed to pay Synthon Labs for work done related to the ANDA, and also gave Synthon Labs an "ownership interest" in the ANDA, even though Synthon Research had already granted the ownership of the ANDA to Synthon Pharma. Thus, without any agreement or consideration to Synthon Pharma, and after years of work by Synthon Pharma in preparing the product and studies, Synthon Research Ltd. purported to give the ANDA rights to Synthon Labs without regard to the prior agreement giving those same ANDA rights to Synthon Pharma. The agreement between Synthon Research and Synthon Labs giving Synthon Labs the right to market the ANDA product was backdated to January 1, 2004, but was not actually signed until January 2005, apparently after this lawsuit was filed.

After Synthon Labs was established in 2004, Mr. Marchetti worked with individuals at Synthon Pharma in North Carolina to review and finalize the ANDA. As part of this effort related to the ANDA, Mr. Marchetti had ongoing e-mail and telephone contact with individuals at Synthon Pharma in North Carolina, usually several times a day over a period of several months, as well as at least three visits to North Carolina to meet with officials and employees of Synthon Pharma and Synthon Holding. While the ANDA was being prepared, Mr. Marchetti made the decision to include the Paragraph IV certification alleging that the '909 patent was invalid. However, this decision was made on the advice of Mr. Buscher, who was a former in-house attorney for Synthon Pharma, and who had previously provided advice (but no formal opinion) to Synthon Pharma and Synthon Holding regarding the '303 and '909 patents. The Paragraph IV certification was included in the ANDA by Synthon Labs in coordination with Synthon Pharma's efforts in North Carolina

in coordinating and preparing the product itself, the necessary bioequivalence studies, and all other aspects of the ANDA. Other than his involvement in the Paragraph IV certification, Mr. Marchetti's only other role with respect to the ANDA was primarily administrative. In March 2004, Synthon Pharma sent the completed ANDA to Mr. Marchetti with specific instructions directing him to sign, date, and send the documents to the FDA. Mr. Marchetti followed the specific instructions, corrected typographical errors, made copies, signed the ANDA, and drove it to the FDA office in Maryland for filing. After the ANDA was filed, FDA requested additional information and responses from Synthon Labs. Synthon Labs, through Mr. Marchetti, forwarded all communications from FDA to Synthon Pharma in North Carolina. Thereafter, Synthon Pharma coordinated the additional work required by FDA and prepared all responses to the FDA. Synthon Labs has not had any other business operations other than setting up an office and filing the ANDA at issue in this case.

Despite the coordinated effort between Synthon Labs and Synthon Pharma in North Carolina, Synthon Labs contends that it did not have the requisite minimum contacts with North Carolina to establish personal jurisdiction. Synthon Labs attempts to distinguish the "preparation" of the ANDA and the "filing" of the ANDA. Synthon Labs contends that the only relevant act in an infringement lawsuit is the "filing," and that Mr. Marchetti's contacts with North Carolina in "preparing" the ANDA are "exempt." In response, Plaintiff contends that Synthon Labs had ongoing, substantial contacts with North Carolina related to the ANDA, and that this lawsuit does indeed "arise out of" those contacts. Plaintiff also contends that Synthon Labs was created specifically to manipulate jurisdiction, and that it is a related "alter ego" or "agent" of the North Carolina entities which should not be considered separately or used to destroy jurisdiction.

During the hearing in this matter, Defendants' counsel candidly admitted that Synthon Labs was established as a corporate entity in Virginia so that litigation on this ANDA and on future ANDAs would be in the Eastern District of Virginia. Defendants' counsel noted that Synthon Laboratories had "attempted to set up where they would have certainty about where they would be sued" because "they wanted to be sued in the Eastern District of Virginia." (Tr. at 26-27.) Defendants' counsel further noted that "we've gone to this difficulty in setting up this corporation and transacting our activity in such a way to make sure that we are sued there [in the Eastern District of Virginia]" and Defendants did not want to "let all that work go to naught." (Tr. at 27.) Defendants also noted that "it may seem as if this is a matter of us trying to get to what's known as a faster jurisdiction – and we would submit that's an element, but that's part of the strategy of setting up Synthon Laboratories." (Tr. at 28.)

With respect to the § 1404(a) motion, Defendants contend that because Mr. Marchetti and the lawyer who advised him (Mr. Buscher, the former Synthon Pharma in-house counsel) are in Virginia, the Eastern District of Virginia would be a more convenient forum. However, all of the other individuals who researched and prepared the ANDA are in North Carolina, and there is very little information in Virginia other than Mr. Marchetti himself. Mr. Buscher is now an officer of a separate Synthon entity and has substantial connections with the Synthon entities in North Carolina. Moreover, Mr. Buscher is apparently asserting that any information he possesses regarding the ANDA may be covered by attorney-client privilege. Therefore, Plaintiff contends that there is no basis to transfer venue in this case to Virginia.

II. MOTION TO DISMISS OR TRANSFER FOR LACK OF PERSONAL JURISDICTION

A. Personal Jurisdiction Based on “Minimum Contacts”

Personal jurisdiction in patent cases is governed by the law of the Federal Circuit. See Akro Corp. v. Luker, 45 F.3d 1541, 1543 (Fed. Cir. 1995). To establish jurisdiction over a non-resident defendant, jurisdiction must be authorized by the state’s long-arm statute and the exercise of jurisdiction must comport with the due process limits of the Constitution. Id. at 1544. North Carolina’s long-arm statute provides for personal jurisdiction in “any action, whether the claim arises within or without this State, in which a claim is asserted against a party who when service of process is made upon such party is engaged in substantial activity within this State, whether such activity is wholly interstate, intrastate, or otherwise.” N.C. Gen. Stat. § 1-75.4(1)(d). This statute has been interpreted as extending to the full extent permitted by the Constitution. See Christian Science Bd. of Directors of the First Church of Christ v. Nolan, 259 F.3d 209, 215 (4th Cir. 2001); Dillon v. Numismatic Funding Corp., 291 N.C. 674, 676, 231 S.E.2d 629, 630 (1977) (“By enactment of G.S. 1-75.4(1)(d), it is apparent that the General Assembly intended to make available to the North Carolina courts the full jurisdictional powers permissible under federal due process”); J.M. Thompson Co. v. Doral Mfg. Co., 72 N.C. App. 419, 424, 324 S.E.2d 909, 913 (1985) (noting that “since the statutory authorization for personal jurisdiction is coextensive with federal due process, the critical inquiry . . . is whether the assertion [of jurisdiction] comports with due process” (internal quotations omitted)). To satisfy due process, the defendant must have certain “minimum contacts” with the forum state “such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice.’” International Shoe Co. v. Washington, 326 U.S. 310, 316, 66 S. Ct. 154, 158, 90 L. Ed. 95 (1945).

Personal jurisdiction over a defendant may be either “general” relating to any course of action or “specific” and related to the particular course of action. For specific jurisdiction, the actions of the defendant in the forum state must relate to the plaintiff’s cause of action. Specifically, the court considers:

- (1) Whether the defendant ‘purposefully directed’ its activities at residents of the forum;
- (2) Whether the claim ‘arises out of or relates to’ the defendant’s activities with the forum; and
- (3) Whether assertion of personal jurisdiction is ‘reasonable and fair.’

See Akro, 45 F.3d at 1545-46. The plaintiff has the burden of proof on the first two prongs. See Inamed Corp. v. Kuzmak, 249 F.3d 1356, 1360 (Fed. Cir. 2001). If it satisfies that burden, the defendant then has the burden on the final prong to establish that the assertion of jurisdiction is unfair or unjust. Id.

Applying this Akro test in the present action, the Court first concludes that Plaintiff has established that Synthon Labs “purposefully directed” its activities at residents of North Carolina. “This ‘purposeful availment’ requirement ensures that a defendant will not be haled into a jurisdiction solely as a result of ‘random,’ ‘fortuitous,’ or ‘attenuated’ contacts, or of the ‘unilateral activity of another party or a third person,’ . . . Jurisdiction is proper, however, where the contacts proximately result from actions by the defendant himself that create a ‘substantial connection’ with the forum State.” Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475, 105 S. Ct. 2174, 2183-84, 85 L. Ed. 2d 528 (1985) (citations omitted). In this case, Mr. Marchetti, the sole officer, director, and employee of Synthon Labs, admits that he had extensive, ongoing telephone and e-mail communications with Synthon Pharma in North Carolina related to the preparation and submission

of the ANDA, usually several times a day for several months.² Defendants also admit that Mr. Marchetti, acting on behalf of Synthon Labs, made multiple trips to North Carolina for meetings at Synthon Pharma with officials of Synthon Pharma and Synthon Holding. Mr. Marchetti worked directly with Synthon Pharma in preparing and submitting the ANDA, and Synthon Labs' only business activity to date has been the preparation and submission of the ANDA in conjunction with Synthon Pharma in North Carolina. Synthon Labs continues to have extensive contacts with North Carolina related to the ANDA, including referring the FDA's inquiries regarding the ANDA to Synthon Pharma in North Carolina. There is no question that Synthon Labs made use of, and continues to make use of, the resources and employees of Synthon Pharma in North Carolina who prepared the ANDA. Based on this activity, the Court finds that Synthon Labs has engaged in substantial activity in North Carolina and has purposefully directed its activities at residents of North Carolina. These activities were not random or attenuated, and Mr. Marchetti's activities on behalf of Synthon Labs have created a substantial connection with North Carolina. Therefore, the Court concludes that Synthon Labs purposefully directed activities at residents of North Carolina within the meaning of the due process inquiry required by Burger King and International Shoe.

Turning to the second prong of the Akro test, the Court finds that Plaintiff's claims against Synthon Labs arise out of and relate to the activities of Synthon Labs in North Carolina. In interpreting this requirement, the Federal Circuit has noted that "the constitutional catch-phrase

² In considering Synthon Labs' contacts with North Carolina, the Court has considered all of the activities by Synthon Labs, through Mr. Marchetti, in both the preparation and the submission of the ANDA. The Court will separately address in detail below Defendants' contention that Mr. Marchetti's contacts with North Carolina related to the preparation of the ANDA should not be considered, based on Defendants' contention that the only relevant act of infringement in this case was the filing of the ANDA.

[‘arise out of or relate to’] is disjunctive in nature,’ indicating ‘added flexibility and signaling a relaxation of the applicable standard’ from a pure ‘arise out of’ standard.” Akro, 45 F.3d at 1547 (quoting Ticketmaster-New York, Inc. v. Alioto, 26 F.3d 201, 206 (1st Cir. 1994)). In Akro, the Court noted that it was appropriate to examine the “quantity, quality and nature of the defendant’s contacts” to determine whether “the contacts are sufficiently connected with the cause of action to satisfy due process.” Id. (quoting B&J Mfg. Co. v. Solar Indus., Inc., 483 F.2d 594, 598-99 (8th Cir. 1973)). Based on this standard, the Court finds that the infringement claims in this case arise out of and relate to the preparation and submission of the ANDA prepared by Synthon Labs and Synthon Pharma in North Carolina. Synthon Labs had substantial contacts with Synthon Pharma in North Carolina working together in preparing the ANDA for submission, and this lawsuit involves Plaintiff’s claims for infringement based on the product described in that ANDA.

However, as previously noted, Synthon Labs contends that this lawsuit only “arises out of or relates to” the submission of the ANDA, not the preparation of the ANDA. Specifically, Synthon Labs contends that 35 U.S.C. § 271(e) makes the submission of the ANDA an act of patent infringement, but that the preparation of the ANDA is not an act of infringement and is therefore exempt from the jurisdictional inquiry. Synthon Labs thus contends that its contacts with North Carolina in preparing the ANDA are “exempt” and should not be considered for jurisdictional purposes because the preparation of an ANDA is not considered “infringement” under 35 U.S.C. § 271(e). Under this argument, Defendants contend that only Synthon Labs’ actual submission of the ANDA should be considered in evaluating the jurisdictional contacts, and not any other acts or contacts undertaken in preparation of the ANDA.

The Court, however, rejects Synthon Labs' contention for several reasons. First, the statutory distinction between the preparation and filing of an ANDA is "highly artificial" with a "very limited and technical purpose." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676-78, 110 S. Ct. 2683, 2691-93, 110 L. Ed. 2d 605 (1990) (noting that 35 U.S.C. § 271(e) achieves "the creation of a highly artificial act of infringement that consists of submitting an ANDA" with a Paragraph IV certification). Defendants have presented no support for the notion that this statutory distinction has jurisdictional implications or that Defendants' contacts related to the preparation of the ANDA become "exempt" from the jurisdictional analysis. Moreover, under Synthon Labs' interpretation, the only relevant jurisdictional contact occurred in Maryland where the ANDA was actually filed. However, the Federal Circuit has held that, even though the ANDA itself is filed in Maryland, the Federal District Court in Maryland may not exercise jurisdiction based solely on its location as the site of the filing of the ANDA. See Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829 (Fed. Cir. 1999). In Zeneca, after determining that the Federal District Court in Maryland could not exercise jurisdiction based on the filing of the ANDA in Maryland, the Federal Circuit Court transferred that case back to the Federal District Court in Pennsylvania, which was where the suit was originally brought and was the place of business of the defendant's parent corporation. Therefore, at least by implication, this Court's jurisdictional inquiry must include consideration of jurisdictional contacts beyond just the filing of the ANDA itself.

Finally, the Court notes that this claim will involve substantial inquiry into the product itself as described in the ANDA, and the focus of that inquiry will involve the work related to the preparation of the ANDA by Synthon Pharma in North Carolina. See, e.g., Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (noting that the focus of the patent

infringement claim is on “what the ANDA applicant will likely market if its application is approved” and “it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder”). Therefore, the claim itself directly involves the work undertaken by Synthon Pharma and Synthon Labs in North Carolina in preparation of the ANDA.

In sum, this Court will not adopt the artificial distinction urged by Synthon Labs and will not “exempt” from the jurisdictional inquiry all contacts other than the actual filing of the ANDA in Maryland. After reviewing all of the contacts, the Court concludes that Synthon Labs had ongoing, extensive contacts with North Carolina directly relating to the preparation of the ANDA. The preparation of this ANDA was, in fact, Synthon Labs’ only business, and was conducted primarily in North Carolina. The Court finds that Plaintiff’s claim arises out of and relates to the ANDA implicated here and any product that might be produced pursuant to that ANDA. Therefore, the Court concludes that it would be appropriate to exercise specific personal jurisdiction over Synthon Labs in this case because the claims in this case relate to and arise directly out of Synthon Labs’ contacts with North Carolina.³

With regard to the final prong of the Akro analysis, the Court finds that the exercise of jurisdiction over Synthon Labs would be reasonable and fair in this case. In a similar case, the Federal Circuit held that exercise of personal jurisdiction over a subsidiary holding company was

³ Moreover, even if only the “filing” of the ANDA is considered, the Court finds that Synthon Labs filed the ANDA in direct coordination with and under direction from Synthon Pharma in North Carolina. Synthon Labs received the final ANDA directly from Synthon Pharma in North Carolina with specific instructions to Mr. Marchetti regarding submission of the ANDA. Synthon Labs submitted the ANDA prepared by Synthon Pharma based on Synthon Pharma’s instructions, and this lawsuit arises directly out of that ANDA.

reasonable and fair. See Dainippon Screen Mfg. Co., v. CFMT, Inc., 142 F.3d 1266 (Fed. Cir. 1998).

The Federal Circuit in Dainippon rejected a similar effort to limit jurisdiction and noted that:

Stripped to its essentials, [defendant] contends that a parent company can incorporate a holding company in another state, transfer its patents to the holding company, arrange to have those patents licensed back to itself by virtue of its complete control over the holding company, and threaten its competitors with infringement without fear of being a declaratory judgment defendant, save perhaps in the state of incorporation of the holding company. This argument qualifies for one of our “chutzpah” awards. . . . While a patent holding subsidiary is a legitimate creature and may provide certain business advantages, it cannot fairly be used to insulate patent owners from defending declaratory judgment actions in those fora where its parent company operates under the patent and engages in activities sufficient to create personal jurisdiction and declaratory judgment jurisdiction.

Id. at 1271. Similarly, in the present case, Synthon Labs cannot establish that the exercise of jurisdiction is unreasonable. Synthon Labs is an indirect wholly-owned subsidiary of Synthon Holding and was created, at least in part, to steer Synthon’s ANDA litigation to the Eastern District of Virginia. The ANDA rights were purportedly transferred to Synthon Labs by an affiliated corporation, without regard to the fact that the ownership rights had already been granted to Synthon Pharma. Synthon’s U.S. operations are headquartered in North Carolina, the work related to the ANDA occurred here, the majority of witnesses are here, and the sole officer and employee of Synthon Labs had regular contacts with affiliated companies here. In these circumstances and in light of the Federal Circuit’s position in Dainippon, this Court concludes that the exercise of personal jurisdiction over Synthon Labs is fair, reasonable, and consistent with due process. Therefore, the Court concludes that Defendant Synthon Labs’ Motion to Dismiss or Transfer for Lack of Personal Jurisdiction [Document #12] should be denied.

B. Personal Jurisdiction Based on Application of the “Alter Ego” Doctrine

Moreover, the Court further concludes that there are significant indications here that Synthon Labs is simply an “alter ego” of Synthon Pharma established by Synthon Holding for jurisdictional purposes. The Federal Circuit has noted that “a court which has jurisdiction over a corporation has jurisdiction over its alter egos.” Minnesota Mining and Mfg. Co. v. Eco Chem, Inc., 757 F.2d 1256, 1265 (Fed. Cir. 1985). Under North Carolina law, affiliated corporations “in which the controlling interest in both is owned by the same person” are considered “alter egos” if “one affiliated corporation is dominated by another to the extent that the dominated corporation has no separate mind, will or identity of its own.” Glenn v. Wagner, 313 N.C. 450, 455-56, 329 S.E.2d 326, 331 (1985). In Glenn v. Wagner, the North Carolina Supreme Court held that two affiliated entities were “alter egos” where the same individual was the president and one of two directors of both companies, with sufficient control to “allow him unilaterally to dissolve” an agreement between the entities. Id. Thus, where an affiliated corporation is operated as a “mere instrumentality or tool,” the courts will exercise their equitable authority to disregard the separate corporate identities. In this analysis, the “[f]ocus is upon reality, not form, upon the operation of the corporation, and upon the defendant’s relationship to that operation.” Id. at 458, 329 S.E.2d at 332.

In Glenn v. Wagner, the North Carolina Supreme Court “enumerated three elements which support an attack on separate corporate entity under the instrumentality rule:

- (1) Control, not mere majority or complete stock control, but complete domination, not only of finances, but of policy and business practice in respect to the transaction attacked so that the corporate entity as to this transaction had at the time no separate mind, will or existence of its own; and
- (2) Such control must have been used by the defendant to commit fraud or wrong, to perpetrate the violation of a statutory or other positive legal duty, or a dishonest and unjust act in contravention of plaintiff’s legal rights; and

- (3) The aforesaid control and breach of duty must proximately cause the injury or unjust loss complained of.”

Glenn v. Wagner, 313 N.C. at 454-55, 329 S.E.2d at 330. This rule applies “when there is evidence of common ownership and actual working control, as in the case of affiliated corporations, taken together with other factors suggesting domination of finances, policy or business practice (including, but not limited to undercapitalization, disregard of corporate formalities, and insolvency).” Id. at 459, 329 S.E.2d at 333. However, “[i]t is not the presence or absence of any particular factor that is determinative. Rather, it is a combination of factors which, when taken together with an element of injustice or abuse of corporate privilege, suggest that the corporate entity attacked had ‘no separate mind, will or existence of its own’ and was therefore the ‘mere instrumentality or tool’ of the dominant corporation.” Id. at 458, 329 S.E.2d at 332.

Applying this analysis to the present case, the Court finds first that the finances, policies and business practices of Synthon Labs were completely dominated and controlled by Synthon Holding and Synthon Pharma. All of these entities are affiliated corporations owned and controlled by Dr. Lemmens. Synthon Holding handled financial information and reporting for Synthon Labs, and Dr. Lemmens, who was also the CEO of Synthon Pharma, provided direct instructions to Mr. Marchetti regarding the business and operations of Synthon Labs. In addition, the entities disregarded agreements among themselves. Specifically, Synthon Research granted ownership of the ANDA to Synthon Pharma and then subsequently granted ownership of that same ANDA to Synthon Labs after the work was completed by Synthon Pharma, without any consideration or agreement between Synthon Labs and Synthon Pharma. Synthon Holding provided capital to Synthon Labs to cover the set-up of the new office, and Synthon Research paid Synthon Labs for

work performed by Synthon Labs related to the ANDA. Significantly, the Court notes that the ANDA was then purportedly transferred to Synthon Labs for no additional consideration.

In addition, with respect to the ANDA at issue in this case, Mr. Marchetti followed specific, explicit directions from his former supervisors at Synthon Pharma, and performed primarily administrative functions at the behest of Synthon Pharma. The ANDA was prepared by Synthon Pharma, and there is no evidence that Synthon Labs has done any work other than set up a small office for Mr. Marchetti where he signed and submitted the ANDA at the behest of Synthon Pharma. To the extent that Mr. Marchetti made the determination regarding the “Paragraph IV certification,” that determination was also made in conjunction with Synthon Holding and Synthon Pharma, and is not a separate transaction from the remainder of the ANDA itself. Synthon Pharma continues to handle all substantive matters in responding to the FDA and handling the ANDA. Therefore, the Court finds that at the time of the filing of the ANDA, Synthon Labs did not have a separate mind, will or existence of its own with respect to the ANDA.

With respect to the second and third prongs of the North Carolina “instrumentality” test, as set out by the North Carolina Supreme Court in Glenn v. Wagner, the Court finds that the control over Synthon Labs was used to commit the “wrong” of patent infringement under 35 U.S.C. § 271(e)(2), and this wrong is the specific injury Plaintiff complains of here. Thus, the control over Synthon Labs was used to “perpetrate the violation of a statutory or other positive legal duty” (as enunciated above in Glenn v. Wagner) because the ANDA was filed at the specific instruction and direction of Synthon Pharma, and the filing of the ANDA was an act of statutory patent infringement.

Moreover, in a similar case, the Federal District Court for the Eastern District of North Carolina applied North Carolina law and held that “later cases have not allowed parent corporations to hide behind the fiction of a subsidiary and enjoy the benefits of a forum while at the same time avoiding the responsibilities attendant therewith. . . . It would be a travesty to allow [defendant] to hold itself out to its shareholders and the public as doing business in North Carolina and, at the same time, selectively avoid process from North Carolina courts at its whim. It is quite obvious to the court that [the subsidiary] was formed for the very purpose of carrying on the business of [the parent].” Federal Deposit Ins. Corp. v. British-American Corp., 726 F. Supp. 622, 629-30 (E.D.N.C. 1989); see also Copley Triangle Associates v. Apparel America, Inc., 96 N.C. App. 263, 264-65, 385 S.E.2d 201, 202-03 (1989) (holding that a subsidiary was the “alter ego” of its parent and shareholders for jurisdictional purposes where the subsidiary was operated under the domination and control of the individual defendants, so that the contacts the defendants had with North Carolina through their alter ego subjected them to North Carolina jurisdiction).

In conclusion, “[w]here an affiliated corporation is without a separate and distinct corporate identity and is operated as a mere shell, created to perform a function for an affiliated corporation or its common shareholders,” the corporate identity should be disregarded. Glenn v. Wagner, 313 N.C. at 457, 329 S.E.2d at 331. In this case, Synthon Labs was created solely to file the ANDA for Synthon Pharma and Synthon Holding in an effort to manipulate jurisdiction regarding the ANDA. The Court concludes that Synthon Labs was the alter ego of Synthon Pharma and Synthon Holding, and the Court’s unopposed exercise of jurisdiction over Synthon Pharma and Synthon Holding is sufficient to confer jurisdiction over Synthon Labs. For all of these reasons, the Court concludes that it has personal jurisdiction over Defendant Synthon Labs.

Finally, the Court notes that venue in patent actions is proper where a defendant resides. See 28 U.S.C. § 1400(b). The Federal Circuit holds that a defendant “resides” in a district if it is subject to personal jurisdiction there. See VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1583 (Fed. Cir. 1990). Accordingly, venue is proper in any district where the defendants are subject to personal jurisdiction. Because this Court has determined that it has personal jurisdiction over all of the Defendants, venue is proper with this Court. Therefore, Synthon Labs’ Motion to Transfer or Dismiss for Lack of Personal Jurisdiction [Document #12] is DENIED.

III. MOTION TO TRANSFER PURSUANT TO 28 U.S.C. § 1404(a)

With respect to Defendants’ Motion to Transfer pursuant to 28 U.S.C. § 1404(a), that statute provides that “[f]or the convenience of parties and witnesses, in the interest of justice, a district may transfer any civil action to any other district or division where it might have been brought.” In considering a motion to transfer under 28 U.S.C. § 1404(a), the following discretionary factors should be considered by the Court:

“(1) the plaintiff’s initial choice of forum; (2) relative ease of access to sources of proof; (3) availability of compulsory process for attendance of unwilling witnesses, and the cost of obtaining attendance of willing and unwilling witnesses; (4) possibility of a view of the premises, if appropriate; (5) enforceability of a judgment, if one is obtained; (6) relative advantage and obstacles to a fair trial; (7) other practical problems that make a trial easy, expeditious, and inexpensive; (8) administrative difficulties of court congestion; (9) local interest in having localized controversies settled at home; (10) appropriateness in having a trial of a diversity case in a forum that is at home with the state law that must govern the action; and (11) avoidance of unnecessary problems with conflicts of laws.”

Brown v. Flowers, 297 F. Supp. 2d 846, 850 (M.D.N.C. 2003) (quoting Plant Genetic Sys., N.V. v. Ciba Seeds, 933 F. Supp. 519, 527 (M.D.N.C. 1996)). “Unless the balancing of these factors weighs

strongly in favor of the defendant, the plaintiff's choice of forum generally should not be disturbed." Id.

In analyzing these factors in the present case, the balance of factors would support retaining venue in this Court. First, Plaintiff's choice of forum in this district is entitled to consideration, particularly where Plaintiff chose to file in the district where Defendants' United States operations are presently headquartered. In addition, the majority of the documents, background information, and relevant witnesses involved in the ANDA are located in this district. There are at least five Synthon Pharma employees in North Carolina who are most familiar with the subject matter in this case and who will be important witnesses in this case. The only potentially important witness in Virginia is Mr. Marchetti, who is an officer of Defendant Synthon Labs and who had extensive contacts with North Carolina related to this suit.⁴ In contrast, the non-officer employees of Synthon Pharma would not necessarily be subject to the subpoena power of the Federal District Court in Virginia. See Fed. R. Civ. P. 45 (noting that a subpoena shall be quashed or modified if it "requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person"). Therefore, the Court concludes that access to sources of proof and witnesses, as well as the ability to compel the attendance of necessary witnesses, would favor venue in this district. The

⁴ Defendants also contend that Mr. Buscher, the attorney who provided the patent opinion to Synthon Labs, is also a relevant witness located in Virginia. However, Mr. Buscher is now the sole officer and employee of a separate Synthon entity, and appears to be claiming attorney-client privilege with respect to his work for Synthon Labs. The Court concludes that even if Mr. Buscher is considered as a potential witness, his presence in Virginia is insufficient to show that the balance of factors weighs in favor of transferring this case.

remainder of the factors appear to be neutral, and thus the balance of factors weighs in favor of retaining venue in this Court.

Finally, the Court declines to transfer this case to the Eastern District of Virginia based solely on the notion that the case would be handled quickly there. Not every patent case is appropriately transferred to that court. To the extent that there are concerns regarding administrative difficulties or the congestion of dockets, this Court will make every effort to expedite this matter and will direct the Court administrators to set this case for trial during the Court's April 2006 trial session. This timing is sufficient to protect Defendants' interests, based on the timeline anticipated by the parties.

For all of these reasons, the Court concludes that the balancing of the relevant factors favors retaining venue in this Court, and Defendants' Motion to Transfer pursuant to 28 U.S.C. § 1404(a) [Document #21] will be denied.

IV. CONCLUSION

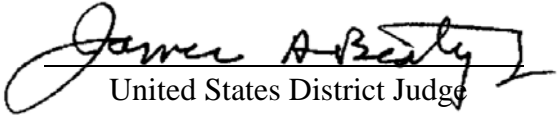
For the reasons discussed above, the Court finds that Synthon Labs had significant contact with North Carolina and worked with affiliated entities in North Carolina to prepare and submit the ANDA at issue in this case. This lawsuit relates to and arises directly out of that ANDA and those contacts. The exercise of jurisdiction does not offend fundamental notions of fairness and substantial justice. Therefore, this Court has specific personal jurisdiction over Synthon Labs with respect to the patent infringement claim being asserted by Plaintiff in this case. In addition, the Court finds that Synthon Labs was an "alter ego" dominated and controlled by Synthon Pharma and Synthon Holding. Therefore, on this basis as well, this Court has personal jurisdiction over Synthon

Labs as the alter ego of the North Carolina entities described herein. For both of these reasons, Defendant Synthon Labs' Motion to Dismiss or Transfer [Document #12] is DENIED.

Finally, with respect to Defendants' Motion to Transfer made pursuant to 28 U.S.C. § 1404(a), the Court concludes that Defendants have failed to demonstrate that the Eastern District of Virginia would be a more appropriate or convenient forum. Moreover, based upon a review of all the relevant considerations, the Court finds that the balancing of convenience factors favors retaining venue in this Court. Therefore, Defendants' Motion to Transfer Pursuant to 28 U.S.C. § 1404(a) [Document #21] is also DENIED.

An Order consistent with this Memorandum Opinion will be filed contemporaneously herewith.

This, the 7th day of September, 2005.


United States District Judge